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EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/042,312

Examiner

Carolyn L. Smith

Applicant(s)

YAHIRO, KANJI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Claims herein under examination are 1-15.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-10 are rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter. As written, the claims appear to be directed to a method that merely manipulates numbers, abstract concepts or ideas, or signals representing any of the foregoing.

As stated in MPEP § 2106, (IV)(B)(1), if the “acts” of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. *Schrader*, 22 F.3d at 294-95, 30 USPQ2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

In practical terms, claims define nonstatutory processes if they:

- consist solely of mathematical operations without some claimed practical application (i.e., executing a “mathematical algorithm”); or
- simply manipulate abstract ideas, e.g., a bid (*Schrader*, 22 F.3d at 293-94, 30 USPQ2d at 1458-59) or a bubble hierarchy (*Warmerdam*, 33 F.3d at 1360, 31 USPQ2d at 1759), without some claimed practical application.

Claims 6-10 do not fulfill any of these statutory requirements and are therefore rejected under 35 U.S.C. 101 because the claims are directed to non-statutory subject matter.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claims 1 (lines 7 and 10), 6 (lines 7, 10, and 11), and 11 (lines 9, 12, and 13) recite the terms “conform(s) to”, “conforming to”, and “conform” which are vague and indefinite. It is unclear what criteria must be met and to what degree in order for the act of conforming to be considered to have occurred. One of skill in the art may interpret the act of conforming or not is merely meeting the condition criteria or not. However, conforming may mean that something is *similar*, but not necessarily identical, to something else. Another interpretation of conforming is that something is *identical* to something else. These various interpretations of conformation result in a vague and indefinite issue regarding the terms mentioned above. Clarification of the metes and bounds of the claims via clearer claim wording is requested. Claims 2-5, 7-10, and 12-15 are also rejected due to their dependency from claims 1, 6, and 11.

Claims 2 (line 3), 7 (lines 2-3), and 12 (lines 2-3) recite the phrase “at least one of a number of the cell and an area of the cell” which is vague and indefinite. It is unclear what this phrase means for various reasons. First, it is unclear if the “at least one of” is directed to both at least one number of the cell and at least area of the cell, if “at least one of” is directed to only one of either the number of the cell or the area of the cell, or if “at least one of” is directed to only a number of the cell. Second, it is unclear what “number of the cell” is intended to mean, as the cell area is also considered to be a number. Third, it is unclear if the area of the cell is intended to mean a particular region of the cell or if the cell area is intended to mean the mathematical area dimensional unit of the entire cell. Clarification of these issues via clearer claim wording is requested.

Claims 4 (line 2), 9 (line 2), and 14 (line 2) recite the phrase “relating to” which is vague and indefinite. It is unclear what criteria must be met and to what degree in order for the relating conditions to be considered present.

Claims 5 (lines 3-4), 10 (line 3), and 15 (line 3) recite the phrase “at least one of a length and an area” which is vague and indefinite. It is unclear if the “at least one of” is directed to both at least one length and at least area, if “at least one of” is directed to only one of either length or area, or if “at least one of” is only directed to a length of the linear structure. Also it is unclear if “an area” is intended to include a particular region of the linear structure or if “an area” is intended to mean the mathematical area dimensional unit of the entire linear structure. Clarification of these issues via clearer claim wording is requested.

Claims 6 (line 11) and 11 (line 13) recite the phrase “judged not to conform” which is vague and indefinite. It is unclear to what the measuring is judged not to conform. One of skill

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in the art may interpret the act of conforming or not is merely meeting the condition criteria or not. However, conforming may mean that something is *similar*, but not necessarily identical, to something else. Another interpretation of conforming is that something is *identical* to something else. These various interpretations of conformation result in a vague and indefinite issue regarding the phrase mentioned above. Clarification of this issue via clearer claim wording is requested.

Priority

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-9, and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilhelm et al. (P/N 5,715,327).

Wilhelm et al. disclose a method performed on an automated microscope system and evaluation apparatus for determining whether a slide containing a biological sample is suitable

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for processing (abstract). Wilhelm et al. disclose taking an image of the biological sample on the slide, processing the slide, determining whether the slide is suitable based on parameters, and whether a threshold (predetermined condition) has been exceeded (Figure 2). Wilhelm et al. disclose the biological sample includes a cell and the parameters (predetermined conditions) including cell ratios (cell numbers) and rings around the cell nuclei (area of the cell) (abstract and Figure 4) as stated in instant claims 2, 7, and 12. In Figure 1A, Wilhelm et al. disclose a calibration slide 524 (reference image). Wilhelm et al. disclose detecting intermediate cell ratios and reference cell ratios (col. 2, line 22) which are reasonably interpreted as a reference image compared to the test slide in the measuring area, as stated in instant claims 3, 8, and 13. Wilhelm et al. disclose a slide suitability score which results from analyses applied to measurements of the slide's characteristics and an automated cytology system's effectiveness (col. 1, lines 10-12), which represent predetermined values resulting from a comparison between the test slide image and the reference slide image, as stated in instant claims 4, 9, and 14.

Wilhelm et al. disclose the apparatus includes an imaging system, a motion control system (measuring area changing unit), an image processing system (condition determining unit and digitizing unit), a central processing system, and a workstation (col. 3, lines 49-52 and col. 4, lines 23-26 and 37-42). Wilhelm et al. disclose the motor drivers position the slide under the optics (col. 4, line 9) and that measurements are taken on requested fields of view (col. 1, lines 17-18) so that the motor driver is reasonably interpreted to be a measuring changing unit that changes the measuring area, as stated in instant claim 1. Wilhelm et al. disclose a hard disk (col. 4, line 17) that represents a storage medium, as stated in instant claims 11-15. Wilhelm et al. disclose the processes are implemented in software (computer program for executing a digital

processor) (col. 4, lines 33-37). Wilhelm et al. disclose a central computer that controls the microscope and processor to acquire and digitize images from the microscope (col. 4, lines 23-26). The computer controls the microscope stage to position the specimen where one to fifteen field of view processors receive images (col. 4, lines 28-32). Wilhelm et al. disclose the flatness of the slide may be checked prior to slide suitability testing (col. 4, lines 23-32) which represents a determination if the slide conforms to a predetermined condition, as stated in instant claim 1. The processor computes a suitability score that indicates whether a slide has passed or failed (condition pass/fail determining unit) in any one of the thirteen suitability tests, as stated in instant claim 1. Wilhelm et al. disclose creating an image of the slide, measuring a suitability parameter, and then checking if the parameter exceeds a predetermined threshold (col. 5, lines 28-34) which represents a condition being previously set and judging whether the measuring area (image) conforms to the condition, as stated in instant claims 6 and 11. Wilhelm et al. disclose a slide must pass all tests in order to be suitable for reporting results (col. 4, lines 39-40) which represents acquisition of data judged to conform to the condition, as stated in claims 6 and 11. Therefore, if a slide does not pass all tests, then processing is considered unsuitable and result processing must cease (col. 4, lines 39-40 and col. 5, lines 24-27 and 40-44) which means that the measuring area does not conform and will no longer be considered which is reasonably interpreted to be a change in the measuring area performed by the automated microscope system, as stated in instant claims 6 and 11. Wilhelm et al. disclose clinicians using normal detected cells as reference cells against which all other cells on the slide can be compared (col. 5, lines 52-54).

Thus, Wilhelm et al. anticipate the limitations in claims 1-4, 6-9, and 11-14.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilhelm et al. (P/N 5,715,327) in view of Sammack et al. (US 2001/0041347).

Wilhelm et al. describe the limitations of claims 1-4, 6-9, and 11-14 (see 102 (b) rejection above). Wilhelm et al. do not describe the biological sample as a cell having a linear structure extending from a soma and the numerical data including at least one of a length and an area of the linear structure. Due to the unclarity of the phrase “at least one of a length and an area of the linear structure”, this phrase has been interpreted to mean either a length or an area of the linear structure. One definition of “soma” is cell body that is defined on the online Merriam-Webster Dictionary as the nucleus-containing central part of a neuron exclusive of its axons and dendrites.

Sammack et al. describe automated systems, methods, screens, and software for the analysis of cell spreading via measurements calculated from cell images (abstract). Sammack et al. describe cells that include proteins that label microtubules fused to a luminescent protein. As the Merriam-Webster Dictionary defines microtubules as “any of the minute tubules in eukaryotic cytoplasm that are composed of the protein tubulin and form an important component

of the cytoskeleton”, Sammack et al. describe labeled MAP4 (microtubule-associated protein 4) and MAP2 that can serve as an indicator of the localization (area), organization, and integrity of microtubules (linear structures) (page 30, paragraphs 0333-0334). MAP2 is expressed specifically in neuronal cells (page 30, paragraph 0334) which is reasonably interpreted to be an indicator of the presence (area) of the linear structures of microtubules found in a neuron. In Figure 9, Sammack et al. describe locating an object in a field (110) and if it does not meet valid cell criteria, then the rest of the current field is searched for unprocessed objects (113) which represents a changing of measuring area because previous area did not conform, as stated in instant claims 6 and 11. In Figure 9, if the current plate is not finished (114) then other wells are found (115) and the stage is advanced to the next well (116) which also represents a changing in measuring area, as stated in claims 6 and 11.

Wilhelm et al. state if a particular slide is anomalous, or if the automated cytology system did not operate effectively on the slide, it would be desirable to flag the unacceptable machine condition or slide characteristic so that potentially false results are not used (col. 1, lines 25-30). Wilhelm et al. state that various modifications could be made to their invention without departing from the scope of the invention (col. 8, lines 31-36). Sammack et al. state their invention is in the field of fluorescence-based cell and molecular biochemical assays for drug discovery (page 1, paragraph 0002). Sammack et al. state that drug discovery is a slow and costly process (page 1, paragraph 0004). Sammack et al. state it is necessary to provide new technologies to rapidly screen disease associated sequences to establish biological function to improve target validation and candidate optimization in drug discovery (page 1, paragraph 0005). Sammack et al. state there is a need to acquire, manage, and search multi-dimensional

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information from cells (page 1, paragraph 0006). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make improvements to drug discovery techniques of drug targets, as stated by Sammack et al., by automating cytology scoring and eliminating false results, as stated by Wilhelm et al., because this would provide higher throughput tools of extracting multiple parameter information in automated systems, as stated by Sammack et al. (page 1, paragraph 0006). Therefore, it would have been obvious to one of ordinary skill in the art to improve efficiency of cytology automated procedures for determining suitability of slides, as stated by Wilhelm et al. by miniaturizing methods involving nerve cells and other drug targets, as stated by Sammack et al., in order to improve drug discovery with increased throughput while decreasing volumes of reagents and test compounds required in each assay, as stated by Sammack et al. (page 1, paragraph 0006).

Thus, Wilhelm et al., in view of Sammack et al., motivate the claims in the instant invention.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

December 29, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER